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10/734,849	12/11/2003	Amr Salahieh	1001.1548101	1994
28075	7590	10/19/2007		
CROMPTON, SEAGER & TUFTE, LLC			EXAMINER	
1221 NICOLLET AVENUE			EREZO, DARWIN P	
SUITE 800				
MINNEAPOLIS, MN 55403-2420			ART UNIT	PAPER NUMBER
			3773	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/734,849

Applicant(s)

SALAHIEH ET AL.

Examiner

Darwin P. Erez

Art Unit

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 and 38-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 22-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/04;12/9/04;7/6/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in the reply filed on 8/1/07 is acknowledged.
2. Claims 17-21 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/1/07.
3. Claims 38-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4/27/07.

Information Disclosure Statement

4. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. **See MPEP 609.05(b)**. Applicant is requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action."

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 26 recites the limitation "the first lumen of said distal sheath includes a first port... and wherein the second lumen of said distal sheath includes a second port".

This contradicts the limitation of the independent claim 1, which recites "an elongated tubular member extending distally to a distal sheath, the elongated tubular member defining a first lumen... and a second lumen". The limitation in claim 1 merely states that the tubular member extends to a distal sheath. It does not recite that the distal sheath includes the first and second lumens. Thus, claims 26-28 are rendered indefinite.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1-3, 5-16 and 22-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,290,710 to Cryer et al.

Fig. 6 of Cryer discloses a filter system, comprising a guide tip **48** having a lumen therethrough; an elongated wire **40** having a distal end attached to the guide tip; an embolic protection filter **42** disposed along the elongated wire; and an elongated tubular member **32** having a first lumen **36** adapted to receive the elongated wire, and a second lumen **38** adapted to receive the guidewire. Cryer is silent with regards to the filter being collapsible within tubular member during use. Instead, Cryer discloses a proximal sheath **50** for holding the filter. This is a mere reversal of the claimed invention. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the proximal sheath to be a distal sheath since it has been held that a mere reversal of essential working parts of a device involves only routine skill in the art. *In re Gazda*, 219 F.2d, 449, 104 USPQ 400 (CCPA 1955). Furthermore, Cryer discloses another embodiment in Fig. 7, wherein the sheath is configured as a distal sheath. Thus, there is motivation to switch the location of the sheath since it determines the direction of the deployed filter **42**.

Cryer further discloses the filter system having guide tip that is tapered (Fig. 6); wherein the proximal portion of the guide tip has a larger profile than the distal (as a result of the tapering); wherein the guidetip includes a guidewire with a spring coil, which would be obvious to be radiopaque since it is well known in the art for guidewires to be made of metal, including the spring coil; wherein the guide tip has an atraumatic distal portion and a straight lumen (Fig. 6), wherein the cross-section of the lumen will

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show a curved profile); wherein the elongated wire fits within a tapered hole in the guidetip via an attachment means (Fig. 6); wherein the guide tip has a joint between the two lumens (a place where two things are joined); wherein the filter is capable of being self deployed when removed from the sheath; wherein the modified invention above would have the proximal portion of the guide tip configured to slide within the sheath; wherein the modified sheath has a skived region with a collar (as seen in Figs. 7 and 8); wherein the system has a loading tool for deployment into the vascular system; wherein the elongated member has a first port and a second port ; wherein the guidetip and the elongated member are aligned via elements 38 and 40, which act as a key to keep the lumens aligned; wherein the modified sheath along with the elongated member with multiple lumens is capable of acting as a retrieval sheath.

Cryer is silent with regards to the second port being located proximally to the first port. Instead, Cryer discloses the first port and the second port being located at the same location. However, it would have been an obvious matter of design choice to one of ordinary skill in the art at the time the invention was made to have the second port be located proximally of the first port since the recited limitation does not provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with either the first and second port being located at the same distance or the claimed limitation because both arrangement will perform the same function of holding the guidewire and the elongated wire.

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11. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cryer et al., and in view of US 6,371,970 to Khosvari et al.

Cryer discloses all the limitations of the claims except for the guide tip having a radiopaque marker band. However, Khosvari discloses a similar invention, wherein a marker band is provided at a guidetip of the device (col. 6, lines 39-50). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Cryer to include a marker band because it would allow the practitioner to monitor the position of the filter system when deployed within the vascular system.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez who's telephone number is (571) 272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/
Examiner
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